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No. 06-1249

In the Supreme Court of the United States

WYETH,

Petitioner,

v.

DIANA LEVINE,

Respondent.

On Writ of Certiorari to the Supreme Court of Vermont

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF THE *AMICUS CURIAE*[1]

The Chamber of Commerce of the United States of America (the Chamber) is the world's largest business federation. The Chamber represents an underlying membership of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases that raise issues of vital concern to the Nation's business community.

This is such a case. The Chamber's members include not only pharmaceutical companies, which depend on the doctrine of implied preemption as protection against state and local mandates that conflict with labeling requirements imposed by federal law, but also millions of other businesses that are subject to preemptive federal statutes and regulations. The Supremacy Clause of the Constitution, which is the fountainhead of the doctrine of implied conflict preemption, serves a

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[1] The parties' letters of consent to the filing of this brief have been filed with the Clerk. Under Rule 37.6 of the Rules of this Court, *amicus curiae* states that no counsel for a party has authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than the *amicus curiae*, its members, or its counsel, has made a monetary contribution to this brief's preparation or submission.

vital structural role in our Nation's government by protecting federal law and programs against encroachment and interference by subordinate governments. It also helps to create unified and rational markets for nationally distributed goods and services by ensuring that uniform federal regulation is not undermined or subverted by state and local law, including state tort law as applied by lay juries. Accordingly, the Chamber and its members have a substantial interest in ensuring that this Court properly resolves the important issues raised in this case.

STATEMENT

1. The Supremacy Clause of the Constitution provides: "This Constitution, and the laws of the United States . . . and all Treaties . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby; any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2. State and local laws that conflict with federal law are preempted "by direct operation of the Supremacy Clause." *Brown* v. *Hotel & Restaurant Employees & Bartenders Int'l Union Local 54*, 468 U.S. 491, 501 (1984).

This Court's decisions interpreting the Supremacy Clause – and articulating what has come to be known as the doctrine of implied conflict preemption – stretch back to the earliest days of the Republic. See, *e.g.*, *Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1 (1824); *Houston* v. *Moore*, 18 U.S. (5 Wheat.) 1 (1820); *M'Culloch* v. *Maryland*, 17 U.S. (4 Wheat.) 316 (1819). "[S]ince our decision in *M'Culloch*," the Court has explained, "it has been settled that state law that conflicts with federal law is 'without effect.'" *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 516 (1992).

The Court's precedents have separately discussed "'conflicts' that prevent or frustrate the accomplishment of a federal objective" (so-called "obstacle" preemption) and "'conflicts' that make it 'impossible' for private parties to comply with both state and federal law" ("impossibility" preemption). *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 873-74 (2000). In *Geier*, this Court recently refused to "drive[] a legal wedge" between the doctrines of obstacle and impossibility preemption, reaffirming its longstanding understanding that "both forms of conflicting state law are 'nullified' by the Supremacy Clause." 529 U.S. at 873-74; *id.* at 874 ("We see no grounds . . . for attempting to distinguish among types of federal-state conflict for purposes of analyzing whether such a conflict warrants pre-emption in a particular case.").

This Court's *test* for obstacle preemption has been the same for more than 65 years, and is derived from *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941): The Supremacy Clause nullifies state or local law that "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." See also *Perez* v. *Campbell*, 402 U.S. 637, 649-50 (1971) ("Since *Hines* the Court has frequently adhered to this articulation of the meaning of the Supremacy Clause.") (citing multiple cases). But the *doctrine* of obstacle preemption is much older than *Hines*, and indeed goes back to this Court's earliest preemption decisions. See *Perez*, 402 U.S. at 649 (obstacle preemption has roots extending at least back to *Gibbons* v. *Ogden*, which recognized that state laws that "'*interfere with*, or are contrary to the laws of Congress . . . ,' are invalid under the Supremacy

Clause") (quoting 22 U.S. (9 Wheat.) at 211) (emphasis added).[2]

Obstacle preemption can occur not only where the goals of state and federal law are incompatible, but also where state law "interferes with the *methods* by which the federal statute was designed to reach [its] goal." *International Paper Co.* v. *Ouellette*, 479 U.S. 481, 494 (1987) (emphasis added). Thus, as with other forms of implied conflict preemption, "[t]he fact of a common end hardly neutralizes conflicting means." *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363, 379 (2000).

2. This case arises out of a medical incident in which a physician assistant inadvertently injected Phenergan, an anti-nausea drug manufactured by petitioner Wyeth, into an artery (rather than as intended, into a vein) in the arm of respondent Diana Levine. In four separate places, Phenergan's two-page label warned of the risk of gangrene arising from arterial exposure. For example, the "Warnings" section cautioned that "extreme care should be exercised to avoid . . . inadvertent intra-arterial injection" because its "likely" consequences would be "pain" and "gangrene requiring amputation." JA 390. Although Phenergan's

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[2] See also *Houston*, 18 U.S. (5 Wheat.) at 22-24 (Supremacy Clause overrides state laws whenever their enforcement would "thwart[]" or "oppose[]" the "will of Congress," even if they do not contradict federal law); *M'Culloch*, 17 U.S. (4 Wheat.) at 427 ("It is of the very essence of [federal] supremacy, to remove all *obstacles* to its action within its own sphere, and so to modify every power vested in subordinate [state] governments, as to exempt its own operations from their . . . influence.") (Marshall, C.J.) (emphasis added); *Savage* v. *Jones*, 225 U.S. 501, 533 (1912) (a "state law must yield" if it prevents "the purpose of" a federal law from being accomplished or "frustrate[s]" the federal law's "operation").

labeling specified a maximum dosage of 25 mg for nausea and instructed that intravenous (IV) injection should be "stopped immediately" if the patient complains of pain, JA 390-91, the physician assistant gave respondent a 50 mg dose – twice the maximum – and administered it without pausing in spite of respondent's complaints of pain. JA 105, 110-11, 183.

After settling a medical malpractice suit, respondent filed this product liability action against Wyeth in the Vermont courts. Respondent's theory of liability was that Phenergan was "not reasonably safe for intravenous administration" through a method known as "IV push" – in which a syringe pushes the medication directly into the patient's vein (or into the flexible tubing of an infusion set already inserted in the vein), as opposed to "IV drip," in which the medication is added to a hanging IV bag of saline solution – because the risks of IV push administration outweighed its "therapeutic benefits." Accordingly, respondent claimed, Wyeth should have included a categorical statement in the drug's labeling to the effect that the drug should *not* be used intravenously (at least not through the IV push method). A Vermont jury awarded respondent approximately $7 million in damages.

The Food and Drug Administration (FDA) approved Phenergan for marketing in 1955.[3] Phenergan's labeling lists both IV and intramuscular (IM) injection as approved methods of administration.

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[3] As petitioner's brief demonstrates (at 11-16), in the 45 years between that approval decision and the medical incident involving respondent, the FDA extensively regulated Phenergan's labeling – including, specifically, both the label's statements concerning the risks attendant to inadvertent intra-arterial injections and its instructions about how to minimize the risk of intra-arterial injections.

JA 390. The FDA's approval of both methods reflects the agency's expert judgment, based on its evaluation of scientific data, that both methods are safe and effective. As Phenergan's labeling notes, IV administration produces clinical effects four times faster than IM administration, and thus is beneficial for certain patients, including those in need of rapid relief. JA 390. Earlier on the day of the medical incident, respondent had received an IM injection of Phenergan, but had returned to the health clinic because that injection had not provided her with relief. JA 19; Pet. App. 2a.

In affirming, a divided Supreme Court of Vermont rejected Wyeth's arguments that respondent's claims were impliedly preempted. Pet. App. 1a-48a. Wyeth argued that respondent's claims both rested on duties that it was impossible for Wyeth to honor without violating federal law, and also frustrated the purposes of the Food, Drug, and Cosmetic Act (FDCA) labeling requirements as implemented by the FDA. The majority acknowledged that (1) "FDA regulations mandate the general format and content of all sections of labels . . . as well as the risk information each section must contain"; (2) the FDA's approval of a new drug application is "conditioned upon the applicant incorporating the specified labeling changes exactly as directed"; and (3) "[o]nce a drug and its label have been approved, any changes to the label ordinarily require submission and FDA approval." Pet. App. 9a (internal quotation marks omitted). Nevertheless, "[w]hile specific federal labeling requirements and state common-law duties might otherwise leave drug manufacturers with conflicting obligations," the court reasoned, a "key FDA regulation" – 21 C.F.R. § 314.70 – "allows, and arguably encourages, manufacturers to add and strengthen warnings that, despite FDA

approval, are insufficient to protect consumers." Pet. App. 10a-11a. Relying on that reading of Section 314.70, which is commonly known as the "Changes Being Effected" (or "CBE") regulation, the Vermont Supreme Court rejected Wyeth's argument of impossibility preemption. Pet. App. 16a-19a.

The lower court also rejected Wyeth's argument based on obstacle preemption. Pet. App. 19a-24a. In so doing, it relied largely (*id.* at 21a-23a) on a provision added to the FDCA in 1962, which states: "Nothing in the amendments made by this Act to the [FDCA] shall be construed as invalidating any provision of State law . . . unless there is a *direct and positive* conflict between such amendments and such provision of State law." Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962) ("Section 202") (emphasis added). In the majority's view, the highlighted language reflects an intent on Congress's part to bar the operation of "obstacle" preemption with respect to the FDCA while preserving the operation of "impossibility" preemption. Pet. App. 21a-23a.

Thus, the Vermont Supreme Court's rejection of Wyeth's arguments for obstacle and impossibility preemption rested on the court's reading of a particular federal statute and regulation. But the court's interpretation was also based on secondary rules about how the preemption analysis should be conducted. Specifically, in rejecting both of Wyeth's implied preemption arguments, the Vermont Supreme Court invoked "the presumption against preemption." Pet. App. 14a, 23a. And the court (again relying on its reading of Section 202) declined to give any weight to certain statements made by the FDA relating to preemption and the adverse and disruptive effects of certain state-law product liability lawsuits on the federal regulatory

scheme, thereby avoiding a "difficult question of administrative law" concerning the degree of deference properly owed to the FDA's statements. Pet. App. 25a-28a.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case presents important issues of preemption law that arise in the distinctive setting of the federal government's longstanding oversight and regulation of prescription drugs pursuant to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* The Supreme Court of Vermont ruled that respondent's state-law tort claims do not offend the Supremacy Clause even though they would require Wyeth to alter Phenergan's FDA-approved labeling by adding a statement that IV push administration – a use that the FDA in its expert judgment has determined is safe and effective – should not be employed because its risks outweigh its benefits. That ruling was mistaken. Respondent's claims are a direct challenge to the FDA's labeling judgments, based on state-law duties that are squarely at odds with the requirements of federal law. Respondent's claims are barred by both impossibility and obstacle preemption.

I. The Chamber files this brief in part to address a broader concern that the Vermont Supreme Court's decision reflects a misunderstanding of the vital importance – and deep historical roots – of the doctrine of implied conflict preemption in our constitutional scheme. As this Court has repeatedly recognized, that doctrine flows directly from the Supremacy Clause itself. And both variants of implied conflict preemption that are at issue in this case – impossibility and obstacle preemption – have deep roots in this Court's decisions. This Court has refused to "drive[] a legal wedge" between obstacle and impossibility preemption

and has made clear that there are "no grounds . . . for attempting to distinguish among types of federal-state conflict for purposes of analyzing whether such a conflict warrants pre-emption in a particular case." *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 873-74 (2000). And with good reason: obstacle and impossibility preemption serve equally crucial roles in protecting *all* of federal law and *all* federal regulatory programs from interference by state and local governments.

The lower court's decision appears to reflect a misguided assumption that obstacle preemption is somehow less important or entitled to less respect under the Supremacy Clause. But as the origins of the Supremacy Clause in the Constitutional Convention make clear, the Framers chose to assign responsibility for ensuring the supremacy of federal law to the judicial branch in the first instance. Obstacle preemption is part of that assignment, as this Court's earliest preemption cases recognize. Moreover, recent scholarship has established that the Supremacy Clause is in the form of a "*non obstante*" clause – a directive specifically aimed at judges and instructing them not to read federal laws narrowly to avoid conflicts with state laws under the Supremacy Clause. Concerns expressed by some judges and commentators that obstacle preemption is unduly subjective or discretionary overlook these facts. In addition, the inquiry into obstacle preemption is no more subjective than many other legal issues that judges are routinely called on to decide.

In resolving this important preemption case, the Court should reaffirm the crucial importance of obstacle preemption and provide clearer guidance on how the implied conflict preemption inquiry should (and

should not) be conducted. Such guidance will go far toward clarifying the doctrine of implied preemption in the same way this Court's recent decisions involving express preemption have provided much-needed clarification. See, *e.g.*, *Riegel* v. *Medtronic, Inc.*, 128 S. Ct. 999 (2008).

II. The Vermont Supreme Court's decision rests on multiple legal errors. As Wyeth persuasively demonstrates, the lower court fundamentally misread the several federal statutory and regulatory provisions. *First*, Section 202 does not purport to restrict the ordinary reach of the Supremacy Clause but rather reflects Congress's intent, in passing the 1962 amendments to the FDCA, not to be understood as occupying the entire field of prescription drug regulation to the complete exclusion of the States. The lower court's reading of Section 202 should also be rejected because it is nonsensical. Why would Congress have wished to authorize state and local governments to erect obstacles to, and frustrate the purposes underlying, the Food, Drug, and Cosmetic Act and the FDA's regulatory regime relating to prescription-drug approval and labeling? Moreover, Section 202 is by its express terms limited to the 1962 "amendments." Why would Congress have wished to extinguish obstacle preemption for those amendments but not for the balance of the Food, Drug, and Cosmetic Act? The Vermont Supreme Court did not offer a plausible answer to these questions, and none exists.

Second, the lower court misread and misunderstood the FDA's labeling regulations, and in particular its CBE regulation (21 C.F.R. § 314.70). The Vermont Supreme Court incorrectly thought that Section 314.70 allowed Wyeth to make "unilateral changes to [Phenergan's] drug label[]" without obtaining prior

FDA approval "whenever [Wyeth] believes it will make the product safer." Pet. App. 13a. In fact, the FDA has long interpreted the CBE regulation as permitting changes to labeling *only* where the changes reflect *newly discovered information* about the drug's safety – information that the FDA has not previously considered. The FDA's longstanding interpretation of the CBE regulation is entitled to deference under settled principles of administrative law. See *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997).

In this case, the Court should also give substantial weight to the FDA's 2006 statements relating to preemption and the adverse and disruptive effects of certain state-law product liability lawsuits on the federal regulatory scheme. See 71 Fed. Reg. 3922 (Jan. 24, 2006); Pet. App. 24a. The Court has relied on such agency statements in the past in evaluating whether state law frustrates federal law and agency programs. See *Medtronic Inc.* v. *Lohr*, 518 U.S. 470, 496 (1996); *Geier*, 529 U.S. at 883. Such reliance makes eminent sense especially where, as here, determining whether state law stands as an obstacle to a complex federal regulatory scheme requires an understanding not only of how the scheme works and affects the real-world conduct of regulated parties but also of how the imposition of diverse state and local requirements affects that scheme and those regulated parties. The FDA's statements in 2006 about the potentially disruptive and deleterious impact on the public health of certain product liability lawsuits are persuasive and thus deserving of substantial weight in this Court.

Finally, the Vermont Supreme Court was wrong to invoke, at several points in its opinion, the so-called "presumption against preemption." As the Chamber has explained in other recent cases, that presumption

is of doubtful validity generally, has been invoked by this Court (albeit inconsistently and controversially) when analyzing claims of *field* and *express* preemption, and has *no* application in cases involving implied conflict preemption. In resolving this case, the Court should make clear that the presumption is irrelevant to resolving issues of implied conflict preemption.

ARGUMENT

I. The Doctrine Of Implied Conflict Preemption Flows Directly From The Supremacy Clause, Serves A Vital Role in Our Constitutional Scheme, And Was Entrusted To Judicial Enforcement By The Framers

Federal preemption of state and local law is an ordinary, intended – and indispensable – feature of our constitutional scheme. Congress's authority to legislate preemptively pursuant to its powers enumerated in Article I of the Constitution, including the Necessary and Proper Clause, U.S. CONST. art. I, § 8, is beyond dispute and has been described by this Court as "[a] fundamental principle of the Constitution." *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363, 372 (2000).[4] In scores of statutes covering a wide array of

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[4] This constitutional basis is important because it explains why the exercise of preemptive authority by Congress raises no concern under the Tenth Amendment, which provides that "[t]he powers *not delegated* to the United States by the Constitution, nor prohibited by it to the States, *are reserved* to the States respectively, or to the people." U.S. CONST. amend. X (emphasis added). "If a power *is* delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States; if a power is an attribute of state sovereignty reserved by the Tenth Amendment, it is necessarily a power the Constitution has *not* conferred on Congress." *New York* v. *United States*, 505 U.S. 144, 156 (1992) (emphasis added).

subjects, Congress has elected to include provisions that expressly preempt state and local law.

Moreover, it is beyond dispute that Congress's handiwork has a preemptive effect even in the absence of such express preemption provisions. This result flows directly from the Supremacy Clause of the Constitution, which the Framers included to remedy glaring shortcomings in the Articles of Confederation. One legal scholar has aptly summarized those shortcomings:

> In the absence of something like the Supremacy Clause, state courts might have sought to analogize federal statutes to the law of a foreign sovereign, which they could ignore under principles of international law. . . . Article XIII [of the Articles of Confederation] had specified that "every State shall abide by the determinations of the United States in Congress assembled, on all questions which by this confederation are submitted to them." But this language did not necessarily mean that Congress's acts automatically became part of the law applied in state courts; it could be read to mean only that each state legislature was supposed to pass laws implementing Congress's directives. If a state legislature failed to do so, and if Congress's acts had the status of another sovereign's law, then Congress's acts might have no effect in the courts of that state. . . .
>
> [Moreover,] [t]he Articles had not been ratified by conventions of the people in each state; states had manifested their assent merely by passing ordinary statutes authorizing their delegates to sign the Articles, and many states had not recognized the Confederation in their own constitutions. James

> Madison fretted that as a result, "whenever a law of a State happens to be repugnant to an act of Congress," it "will be at least questionable" which law should take priority, "particularly when the latter is of posterior date to the former."

Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 247-48, 251 (2000) (quoting James Madison, *Vices of the Political System of the United States* (Apr. 1787), in 9 PAPERS OF JAMES MADISON 345, 352 (R. Rutland & W. Rachal eds. 1975)).

To address these structural deficiencies in the Articles, the Framers included the Supremacy Clause, which broadly provides that "the Laws of the United States . . . shall be the *supreme* Law of the Land . . . *any* Thing in the Constitution or Laws of *any* State *to the Contrary notwithstanding*." U.S. CONST. art. VI, cl. 2 (emphasis added). As a consequence of the Supremacy Clause, all federal laws are automatically preemptive of state and local laws to the extent that the latter impose conflicting obligations or requirements. To understand the importance and vital role of the Supremacy Clause, it is useful briefly to review its genesis during the debates in the Constitutional Convention.

A. The Origins Of The Supremacy Clause

During the Convention, the Founders considered "three mechanisms for resolving conflicts between federal and state law." Bradford Clark, *Separation of Powers As A Safeguard of Federalism*, 79 TEX. L. REV. 1321, 1348 (2001). *First*, the Virginia (or Large State) Plan proposed "authorizing the Union to use military force to coerce the states to comply with federal law." Bradford Clark, *Unitary Judicial Review*, 72 GEO. WASH. L. REV. 319, 325 (2003). But "[t]he delegates

were immediately opposed to the use of force" and "[t]he Convention tabled the proposal and never seriously entertained this alternative." *Id.* at 325-26 & nn.44-47.

Second, the Virginia Plan alternatively recommended "that the National Legislature ought to be impowered . . . to negative all laws passed by the several States, contravening in the opinion of the National Legislature the articles of Union . . . ." James Madison, *Notes on the Constitutional Convention* (May 29, 1787), in 1 THE RECORDS OF THE FEDERAL CONVENTION OF 1787, at 21 (Max Farrand ed. 1911) ("FARRAND'S RECORDS"). Under this "congressional negative" as originally proposed, Congress would have had the power to "negative" all state laws that, in Congress's judgment, violated the federal Constitution. The delegates apparently envisioned the congressional negative, by analogy to the Crown's prerogative to approve Colonial laws, as operating to *prevent* state laws from going into effect *until* Congress acted (except in special circumstances).[5]

Third, the New Jersey Plan included a resolution that "was in substance and concept, if not in form, similar to the current language of the Supremacy Clause." Viet Dinh, *Reassessing the Law of Preemp-*

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[5] See, *e.g.*, 2 FARRAND'S RECORDS 27 (Madison) (arguing that anything short of the congressional negative would be ineffective because it would allow the States to "pass laws which will accomplish their injurious objects before they can be repealed" by Congress or invalidated by the federal courts); *ibid.* (Martin) (in criticizing the proposal, posing the following rhetorical question: "Shall all the laws of the States be sent up to the Genl. Legislature before they shall be permitted to operate?"); *id.* at 390 (Mason) (voicing identical concern); 1 FARRAND'S RECORDS 167 (Bedford) (same).

tion, 88 GEO. L.J. 2085, 2089 (2000). It "would have required state courts (subject to federal appellate review) to enforce the Laws of the United States 'made by virtue & in pursuance of the powers . . . vested in them' as 'the supreme law of the respective States.'" Clark, *supra*, 72 GEO. WASH. L. REV. at 327 (quoting 1 FARRAND'S RECORDS 245).

The Convention initially approved the "congressional negative" in its original form. *Id.* at 326. But Charles Pinckney "moved to expand the negative" by giving Congress the power to negate any state law that Congress regarded as "improper" (rather than merely contrary to the federal Constitution). At that point, the small-state delegates strongly objected, and the Convention not only rejected Pinckney's proposal but also "subsequently reconsidered and rejected even the original congressional negative." *Ibid.* Even though the original congressional negative was "limited on its face," it was unacceptable to a majority of States because it "would have allowed *Congress* to determine for itself the scope of its powers vis-à-vis the states." *Ibid.* (emphasis added).

"Although th[e] 'Supremacy Clause' [in its initial form] was originally rejected as part of the New Jersey Plan, the Convention subsequently adopted the Clause immediately after rejecting the congressional negative." *Id.* at 327. In so doing, the Convention rejected the arguments of James Madison (who had been the primary drafter of the Virginia Plan) that the adoption of the congressional negative was "essential to the efficacy & security of the Genl. Govt." 2 FARRAND'S RECORDS 27. Disagreeing with Madison, Gouverneur Morris explained that any "law that ought to be negatived will be set aside *in the Judiciary departmt.* and if that security should fail; may be *repealed by a Nationl.*

law." *Id.* at 28 (emphasis added). Similarly, Roger Sherman argued that the congressional negative was "unnecessary" because the state courts "would not consider as valid any law contravening the Authority of the Union, and which the legislature would wish to be negatived." *Id.* at 27.[6]

As the foregoing history make clear, the Convention delegates who opposed the congressional negative did so because, among other things, they viewed it as unnecessary once the Supremacy Clause had been included in the Constitution. The Supremacy Clause assigned to *the courts* in the first instance the duty to ensure that state laws that were inconsistent with federal laws would be accorded no effect (and thus preempted). Failing that, Congress could always take further action by passing preemptive laws to address the situation. Thus, the delegates who were critics of the congressional negative *assumed* that Congress would have the authority to preempt state law. See also Dinh, *supra*, 88 GEO. L.J. at 2089-90 (2000) (noting that, in contrast to the congressional negative of the Virginia Plan, which was "proposed as one of Congress' affirmative powers," the Supremacy Clause "is relevant only at the post-enactment stage, where a state law conflicts to some degree with a federal law").

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[6] After the delegates had approved the Supremacy Clause, Charles Pinckney again proposed to add the congressional negative, but this time a version that would have required two-thirds of both houses. 2 FARRAND'S RECORDS 390. In response, Roger Sherman argued that this provision was "unnecessary" because, in light of the Supremacy Clause, the "laws of the General Government" will be "Supreme & paramount to the State laws." *Ibid.* The Convention then voted against committing Pinckney's proposal to committee for further study. *Id.* at 391.

Finally, the specific language of the Supremacy Clause confirms the Framers' intent that it be enforced by the Judiciary. See U.S. CONST. art. VI, cl. 2 ("This Constitution, and the Laws of the United States . . . and all Treaties . . . shall be the supreme Law of the land; and the Judges in every State shall be bound thereby; any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."). The first clause establishes a hierarchy of federal law and authority; the second is expressly directed at "Judges." As for the third clause – "any Thing in the Constitution or Laws of any State to the Contrary notwithstanding" – recent scholarship has established that its form would have been understood by the Framers (and eighteenth-century judges) as a so-called "*non obstante*" clause. Such clauses were understood by the courts as a directive *not* to employ the traditional presumption against implied repeals (which might induce strained interpretations to harmonize a later federal law with an earlier state regulation), but instead to give a federal statute its most reasonable construction and allow it to displace whatever state law it contravened when so construed. See Nelson, *supra*, 86 VA. L. REV. at 232, 235-44, 291-303. The *non obstante* form of the Supremacy Clause, then, suggests that judges should *not* automatically prefer a narrow interpretation of a federal statute to avoid the conclusion that it contradicts (and hence preempts) state laws. *Id.* at 232, 245-64. In other words, the Supremacy Clause is effectively a directive to the judiciary *not* to apply any "presumption against preemption."[7]

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[7] Other scholars and learned commentators have agreed with Professor Nelson on this score. See, *e.g.*, Dinh, *supra*, 88 GEO. L.J. at 2087 ("the constitutional structure of federalism does not admit to a general presumption against federal preemption of state law");

B. This Court's Longstanding Interpretation Of The Supremacy Clause As The Source Of Obstacle And Impossibility Preemption

As explained above (at 2-4), this Court has elucidated the meaning of the Supremacy Clause in a long line of cases involving the doctrine of implied conflict preemption. These cases stretch back almost 200 years. See, *e.g.*, *Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1 (1824); *Houston* v. *Moore*, 18 U.S. (5 Wheat.) 1 (1820); *M'Culloch* v. *Maryland*, 17 U.S. (4 Wheat.) 316 (1819). Both obstacle and impossibility preemption have roots in these early cases. And the Court's decisions consistently have made clear that both forms of conflict preemption rest on an interpretation of the text of the Supremacy Clause itself. See, *e.g.*, *Perez* v. *Campbell*, 402 U.S. 637, 649 (1971) (obstacle preemption is an "articulation of the meaning of the Supremacy Clause").

Illustrative is *M'Culloch*, where Chief Justice Marshall explained that, by virtue of the Supremacy Clause, "the government of the Union, though limited in its powers, is supreme within its sphere of action," so that duly enacted federal statutes must prevail over contrary state laws. 17 U.S. (4 Wheat.) at 405-06, 425-26, 432, 436. Accordingly, the Court held, the State of Maryland could not exercise its general power to tax in a manner that would destroy, impede, or burden the

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Jack Goldsmith, *Statutory Foreign Affairs Preemption*, 2000 SUP. CT. REV. 175, 182 (presumption is "difficult to justify" on constitutional grounds); Paul Clement & Viet Dinh, *When Uncle Sam Steps In: There's No Real Disharmony Between High Court Decisions Backing Pre-emption And The Federalism Push of Recent Years*, LEGAL TIMES, June 19, 2000, at 66 (arguing that the presumption "finds no support in the structure of the Constitution").

operation of a specific agency created by a valid federal law (the Bank of the United States). *Id.* at 425-37. As Chief Justice Marshall explained in language suggestive of obstacle preemption, "It is of the very essence of [federal] supremacy, to remove all *obstacles* to its action within its own sphere, and so to modify every power vested in subordinate [state] governments, as to exempt its own operations from their . . . influence." *Id.* at 427 (emphasis added). See also pages 3-4 & n.2, *supra*.

C. This Court's Unwillingness To Create A Hierarchy Of Types Of Conflict Preemption And The Vital, Independent Functions Of Impossibility And Obstacle Preemption

In addition to long interpreting the Supremacy Clause as the source of both obstacle and impossibility preemption, this Court has sometimes used other verbal formulations to describe state laws that are nullified because they stand in conflict with federal law:

> This Court, in considering the validity of state laws in the light of treaties or federal laws touching the same subject, has made use of the following expressions: conflicting; contrary to; . . . repugnance; difference; irreconcilability; inconsistency; violation; curtailment; and interference. But none of these expressions provides an infallible constitutional test or an exclusive constitutional yardstick.

Hines, 312 U.S. at 67.

Notably, however, the Court has declined to draw a sharp line distinguishing between forms of conflict preemption emanating from the Supremacy Clause. In *Geier* v. *American Honda Motor Co.*, 529 U.S. 861

(2000), for example, this Court rejected the argument that a party claiming *obstacle* preemption should be required to bear a "special burden" when the relevant federal statute includes a "savings" provision:

> The Court has not previously driven a legal wedge – only a terminological one – between "conflicts" that prevent or frustrate the accomplishment of a federal objective and "conflicts" that make it "impossible" for private parties to comply with both state and federal law. Rather, it has said that both forms of conflicting state law are "nullified" by the Supremacy Clause, . . . and it has assumed that Congress would not want either kind of conflict. . . . We see no grounds, then, for attempting to distinguish among types of federal-state conflict for purposes of analyzing whether such a conflict warrants pre-emption in a particular case.

529 U.S. at 873-74 (citations omitted).[8]

This reluctance to create a hierarchy of theories of conflict preemption is understandable, not only because conflicts and inconsistencies between federal and state law can take myriad forms but also because obstacle and impossibility preemption each serve a vital function in our constitutional scheme. Impossibility preemption addresses situations where both federal and

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[8] The Court in *Geier* also gave as a reason for rejecting special treatment of obstacle preemption the fact that such an approach would "promise practical difficulty by further complicating well-established pre-emption principles that already are difficult to apply." 529 U.S. at 873. "That kind of analysis," the Court explained, "would engender legal uncertainty with its inevitable systemwide costs . . . as courts tried sensibly to distinguish among varieties of 'conflict' [preemption] (which often shade, one into the other) . . . ." *Id.* at 874.

state law impose mandates on a regulated party – and it is simply not possible to comply simultaneously with both mandates. If the federal government commands a citizen to do X and a state law requires a citizen *not* to do X (or makes doing X a crime), there is no way to comply with both the federal and state requirements. In that circumstance, the state command must yield. See, *e.g.*, *Southland Corp.* v. *Keating*, 465 U.S. 1, 10, 16 (1984) (Congress's decision to "mandate[] the enforcement of arbitration agreements" preempts California's mandate that such agreements be invalidated in certain situations).

But federal laws and regulatory regimes can be severely undermined and even destroyed even in the absence of such diametrically opposed commands or requirements. If Congress passes a law guaranteeing the right of all workers to join a union, and a State makes it a felony offense to join a union, it is *not impossible* to comply with both laws; by declining to exercise the federally created right, a worker can easily comply with both laws. But the state law in this scenario so clearly undermines and burdens the federal right to join a union – and frustrates the purpose of the federal statute, which is to safeguard the right to join a union and perhaps to encourage union membership – that it obviously cannot stand under the Supremacy Clause.

Indeed, this Court has applied obstacle preemption even when the burden imposed on federal rights was far less dramatic than in this hypothetical example. For example, in *Felder* v. *Casey*, 487 U.S. 131 (1988), the Court ruled that 42 U.S.C. § 1983 preempted a Wisconsin notice-of-claim statute that required a civil rights plaintiff to provide written notice (at least 120 days before filing suit) to putative government defendants of the circumstances giving rise to her constitu-

tional claims, the amount of the claim, and her intent to bring suit. In the absence of such notice, the Wisconsin law required the state courts to dismiss the plaintiff's Section 1983 lawsuit. Writing for the Court, Justice Brennan explained that the Wisconsin statute was barred under the doctrine of obstacle preemption because, among other things, it "burdens the exercise of the federal right by forcing civil rights victims who seek redress in state courts to comply with a requirement that is entirely absent from civil rights litigation in the federal courts." *Id.* at 141; see also *id.* at 138, 144-45. That conclusion necessarily depended on a robust doctrine of obstacle preemption, because it plainly was not impossible to comply with both the Wisconsin statute and the requirements of Section 1983. As *Felder* illustrates, the doctrine of obstacle preemption plays a vitally important role – and a role that complements impossibility preemption – in ensuring the supremacy and full effectiveness of *all* federal laws against incursions and encroachments by the States.

D. This Court's Well-Established Method Of Deciding Conflict Preemption Issues

This Court's general methodology in resolving conflict preemption issues is also well settled. "Deciding whether a state statute is in conflict with a federal statute and hence invalid under the Supremacy Clause is essentially a two-step process of first ascertaining the construction of the two statutes" – federal and state – "and then determining the constitutional question whether they are in conflict." *Perez*, 402 U.S. at 644. In conducting this inquiry, a federal court is bound by the authoritative construction given to the relevant state law by the State's courts. *Ibid.* Moreover, "[t]he relative importance to the State of its own law is *not material* when there is a conflict with valid federal law,

for the Framers of our Constitution provided that the federal law must prevail.'" *Fidelity Fed. Savings & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982) (emphasis added) (quoting *Free* v. *Bland*, 369 U.S. 663, 666 (1962)).

The judicial decision as to exactly when the tension between state and federal laws rises to the level of a "conflict" is a matter of judgment. See *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363, 373 (2000) ("What is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects[.]"). The critical question in each case is the extent of the inconsistency between state and federal law and whether that amount is sufficient, under the Supremacy Clause, to trigger conflict pre-emption.

* * *

Notwithstanding (a) the deep roots of the doctrine of implied conflict preemption in the Supremacy Clause and this Court's decisions, (b) this Court's traditional unwillingness to differentiate between types of federal-state conflicts triggering operation of the Supremacy Clause, and (c) the vital, structural roles played by both obstacle and impossibility preemption in protecting the national government and federal laws from encroachment and subversion by States and localities, some Members of this Court (and some legal scholars) have expressed special concerns about applying the doctrine of obstacle preemption. For example, the dissenters in *Geier* referred to "our potentially boundless . . . doctrine of implied conflict pre-emption based on frustration of purposes" and expressed concern that obstacle preemption vests too much discretion in "unelected federal

judges." 529 U.S. 861, 894, 907 (Stevens, J., dissenting). See also REPORT OF THE APPELLATE JUDGES CONFERENCE, AMERICAN BAR ASS'N, THE LAW OF PREEMPTION 38 (1991) (obstacle preemption "demands a high degree of judicial policymaking").[9]

It is true, of course, that obstacle preemption sometimes requires judges to make subtle judgments about when the tension between state and federal law rises to the level of a preemption-triggering conflict. *Crosby*, 530 U.S. at 373. But those same types of judgments are also required for other forms of implied conflict preemption. True, obstacle preemption often requires judges to identify the congressional "purpose" that allegedly is being thwarted by state law. That task, however, is not an unfamiliar one for judges who routinely engage in the interpretation of statutes. Furthermore, Congress often declares its purposes explicitly in a statute (or in the accompanying legislative materials). Moreover, these judgment calls involve no more discretion than a wide array of other decisions made by federal courts every day. The law is filled with broad concepts – reasonableness, probable cause, excusable neglect, good cause, ordinary care – that call for the judicial exercise of judgment.

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[9] The principal author of the ABA Report has explained that his views on the doctrine of preemption have changed in response to fundamental changes in the legal landscape that have occurred since 1991. See Kenneth Starr, *Preface*, in FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS xi, xv (R. Epstein & M. Greve eds. 2007); see also *id.* at xvi (suggesting that Congress "cannot possibly police and redress every improper incursion on federal authority by legislative, executive, and judicial branches of all 50 state governments" and concluding that, "[i]f that job is to be done at all, it must be the federal judiciary that does it").

Beyond that, as the foregoing discussion of the Constitutional Convention makes clear, the Supremacy Clause is by design a provision that is meant to be *enforced by the courts* (in contrast to the rejected congressional negative, which Congress itself would have employed). Federal courts are the institutions entrusted by the Constitution with the authority to police incursions by the States on the supremacy of federal law. And the tasks that are involved in deciding an issue of implied conflict preemption under this Court's traditional methodology – interpretation of the state and federal laws in question and of the Supremacy Clause – are tasks the judiciary is uniquely suited to undertake. For all of these reasons, this Court should reject any arguments in this case that would either abandon or weaken settled principles of obstacle preemption.

II. This Court Should Reverse The Flawed Decision Below And Clarify The Doctrine Of Implied Conflict Preemption

The Chamber agrees with Wyeth that the Vermont Supreme Court's decision rests on several clear errors of law. Specifically, the lower court misinterpreted Section 202 of the Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793, misunderstood an important FDA labeling regulation, 21 C.F.R. § 314.70, and misidentified patient safety as Congress's sole objective in passing the FDCA. Pet. App. 20a. Once these errors are corrected, it is clear that respondent's state-law claims are preempted under both impossibility and obstacle preemption. Despite the availability of this rather narrow ground for decision, the Chamber urges the Court to take this opportunity to clarify the doctrine of implied conflict preemption in several key respects.

A. The Lower Court's Reliance On The Presumption Against Preemption Was Mistaken

In rejecting both of Wyeth's implied preemption arguments, the Vermont Supreme Court specifically invoked "the presumption against preemption." Pet. App. 14a, 23a. As Wyeth demonstrates (Pet. Br. 51 n.23), that rule of construction is irrelevant because the federal government has regulated drug labeling for more than a century. See *United States* v. *Locke*, 529 U.S. 89, 90, 108 (2000) (presumption against preemption "is not triggered when [a] State regulates in an area where there has been a history of significant federal presence").

More fundamentally, the Court should take this opportunity to make clear that the presumption against preemption – whatever its applicability to questions of field preemption – is simply inapplicable to cases involving conflict preemption. In *Warner-Lambert Co.* v. *Kent*, 128 S. Ct. 1168 (2008) (per curiam order), the Chamber filed an *amicus* brief urging this Court to resolve confusion in the lower courts by squarely holding that the presumption does *not* apply to issues of conflict preemption. See Br. of The Chamber of Commerce of the United States of America As *Amicus Curiae*, *Warner-Lambert Co. LLC* v. *Kent*, No. 06-1489, at 8-20. Without repeating all the same arguments here, the Chamber refers the Court to that brief and respectfully renews the same request. As explained above, recent scholarship establishes that the Supremacy Clause is a "*non obstante*" clause that, by its very nature, directs the courts *not* to apply any presumption against preemption. The Court's resolution of this issue would go far toward clarifying the

litigation of implied conflict preemption issues in the lower courts.

B. The Lower Court's Reading Of Section 202 Was Wrong And Nonsensical

As Wyeth persuasively shows (Pet. Br. 51-54), the Vermont Supreme Court misread Section 202 of the 1962 Amendments as extinguishing the doctrine of obstacle preemption in connection with the FDCA and leaving in place only impossibility preemption. In fact, Section 202's function was to make clear that Congress did not intend to occupy the entire field of drug regulation; and its reference to "direct and positive" conflicts was nothing more than a shorthand for implied conflict preemption. Congress thus has demonstrated an intent to *preserve* conflict preemption in all of its forms. The lower court's reading of Section 202 was wrong.

As if that were not enough, the Vermont Supreme Court's interpretation also makes very little sense. In *Geier*, this Court observed it was difficult to believe that Congress, in passing the savings clause at issue there, would "not have wanted ordinary pre-emption principles to apply where an actual conflict with a federal *objective* is at stake." *Id.* at 871 (emphasis added). To hold otherwise, this Court reasoned, would have the effect of "tak[ing] from those who would enforce a federal law the very ability to achieve the law's congressionally mandated objectives that the Constitution, through the operation of ordinary pre-emption principles, seeks to protect" – an outcome that "permits [the federal] law to defeat its own objectives, or . . . destroy itself." *Id.* at 872 (internal quotation marks omitted). The Vermont Supreme Court's reading of Section 202 suffers from a similar credibility gap. Indeed, it is worse, because Section 202 is expressly

limited to the effect of the 1962 "amendments." If that language is to be given its plain meaning, then under the Vermont Supreme Court's interpretation Congress wished to extinguish obstacle preemption with regard to the 1962 amendments but not with regard to other provisions of the FDCA. Why? The Vermont Supreme Court gave no plausible explanation, and there is none.[10]

C. The FDA's Views About The Detrimental Effects Of Recent Product Liability Litigation On Its Regulatory Regime Are Persuasive And Should Be Given Significant Weight

As Wyeth correctly explains (Pet. Br. 34-40), the Vermont Supreme Court's rejection of impossibility preemption rests on a misunderstanding of an FDA labeling regulation, 21 C.F.R. § 314.70, which the parties have referred to as the "CBE" regulation. The lower court thought that provision allowed Wyeth to make "unilateral changes to [Phenergan's] drug label[]" without obtaining prior FDA approval "whenever [Wyeth] believes it will make the product safer." Pet. App. 13a. In fact, the FDA has long interpreted the CBE regulation as permitting changes to labeling *only* where the changes reflect *newly discovered information*

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[10] Because the lower court's reading of Section 202 is plainly wrong, there is no need in this case to address the outer limits on Congress's authority to restrict by statute the doctrine of implied conflict preemption, which as explained earlier (at 2-4, 16-18) flows directly from the Supremacy Clause. Whatever those limits might be, the Court should be very reluctant to infer that Congress, in passing a generally worded provision such as Section 202, intended either to eliminate wholesale the doctrine of obstacle preemption or to authorize the states to obstruct other, more specific federal requirements that remain in place (such as the FDA's labeling requirements).

about the drug's safety – information that the FDA has not previously considered. See also U.S. Br. 13-15 (invitation brief). Because no such new information is at issue in this case, Wyeth simply was not free to alter its labeling in the way the Vermont jury concluded that state law requires.

As Wyeth also demonstrates (Pet. Br. 39), the FDA's interpretation of the CBE regulation is long-standing and entitled to deference under settled principles of administrative law. See *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997). For all the same reasons that a presumption against preemption is inapplicable to the first step in any conflict preemption analysis (in which the court interprets the relevant federal and state laws), courts should apply the ordinary rules relating to deference to administrative agencies' interpretations of the statutes and regulations they administer at this first step of the analysis.

To be sure, a more difficult question arises with respect to the weight that should be given to an administrative agency's views in the *second* step of a conflict preemption analysis – the court's evaluation of the extent of the conflict between state and federal laws and its determination whether the inconsistency rises to the level of a violation of the Supremacy Clause. The Vermont Supreme Court referred to this as a "difficult question of administrative law," which arose with respect to certain statements made in 2006 by the FDA relating to preemption and the adverse and disruptive effects of certain state-law product liability lawsuits on the federal regulatory scheme. See 71 Fed. Reg. 3922 (Jan. 24, 2006); Pet. App. 24a. But the court avoided answering that "difficult question" based on its flawed readings of Section 202 and the CBE regulation.

This Court has already made clear, however, that it is entirely appropriate to afford substantial weight to the views of an administrative agency charged with implementing a comprehensive regulatory scheme in a technical area where, as here, the agency concludes, for persuasive reasons, that state regulation interferes with its regulatory regime or presents an obstacle to the achievement of federal objectives. In *Medtronic Inc.* v. *Lohr*, 518 U.S. 470 (1996), this Court explained that the FDA is "uniquely qualified to determine whether a particular form of state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress . . . and, therefore, whether it should be pre-empted." *Id.* at 496 (internal quotation marks omitted). And in *Geier*, the Court deferred to the Department of Transportation's views concerning the objectives underlying an agency safety standard and the extent to which state law would pose an obstacle to the accomplishment of those objectives. See 529 U.S. at 883-84. "The agency is likely to have a thorough understanding of its own regulation and its objectives," the Court explained, "and is uniquely qualified to comprehend the likely impact of state requirements." *Id.* at 883 (internal quotation marks omitted).

This approach makes eminent sense. The determination whether state law stands as an obstacle to a complex federal regulatory scheme often requires an understanding not only of how the scheme works and affects the real-world conduct of regulated parties but also of how the imposition of diverse state and local requirements affects that scheme and those regulated parties. In many instances, as here, this will involve technical or policy-based judgments about the practical effect of state law on the efficient and effective opera-

tion of a complex statutory and regulatory scheme – judgments that an administrative agency such as the FDA is uniquely well suited to make. Thus, it would make no sense to disregard the FDA's well-founded judgments at the second step of the obstacle preemption inquiry in this case.

In any event, the FDA's statements in 2006 about the potentially disruptive and deleterious impact on the public health of certain product liability lawsuits are quite persuasive and thus deserving of substantial weight in this Court. As the FDA has explained, state-law product liability lawsuits can, in certain circumstances, "directly threaten[] the agency's ability to regulate manufacturer dissemination of risk information," "frustrate the agency's implementation of its statutory mandate," "erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use," spur the communication of "risk information" that is "unsubstantiated" and warnings about "speculative risks," and "potentially discourag[e] safe and effective use of approved products." 71 Fed. Reg. 3934-35. These effects are real, and the FDA's serious concern about their impact on the public health should be accorded substantial weight in determining whether lawsuits such as this one frustrate the purposes underlying the FDCA and the FDA's labeling regulations.

CONCLUSION

The judgment of the Vermont Supreme Court should be reversed.

Respectfully submitted.

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